## REMARKS

Paragraph [0018] of the specification and claims 39 and 43 have been amended to correct informalities contained therein, specifically, the spellings of travoprost and bimatoprost. Claims 11 and 30 have been amended to recite further aspects of the ocular implants recited therein. Support for the amendments to claims 11 and 30 may be found at least at paragraph [0016] of the as-filed specification. Claim 34 has been canceled without prejudice or disclaimer. Claim 35 has been amended to depend from claim 30 rather than claim 34. Claims 45 and 46 have been added and read on the elected species. Support for claims 45 and 46 may be found at least at paragraph [0019] of the as-filed specification. No new matter has been added. Upon entry of this amendment, claims 11, 13-19, 21-33, and 35-46 are pending, with claims 13, 16, 18, 19, 23-28, 32, 35, and 36 withdrawn from consideration at this time.

In the Office Action dated December 28, 2009, the declaration that was filed February 11, 2008 was objected to for not including the mailing address for each inventor. Applicant is filing a Supplemental Application Data Sheet herewith to provide the mailing address for each inventor in accordance with 37 C.F.R. §1.76 to satisfy 37 C.F.R. §1.63(c). Accordingly, Applicant respectfully requests that the objection to the declaration be withdrawn.

In the Office Action, claims 39 and 43 were objected to for the misspelling of travoprost and bimatoprost. Although Applicant respectfully submits that travaprost and bimataprost are known alternative ways to spell travoprost and bimatoprost, as discussed above, claims 39 and 43 have been amended to correct the spellings, as suggested by the Office Action. Accordingly, Applicant respectfully requests that the objection to claims 39 and 43 be withdrawn.

In the Office Action, claim 22 was rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

Claim 22 depends from claim 21 and further recites "wherein the exterior surface portion of the implant body releasing the active agent is configured to provide the sustained release to tissue at or near the eye for a time period between 3-6 months after implant." Applicant

respectfully submits that claim 22 fully complies with 35 U.S.C. §112, first paragraph. *See*, for example, page 4, paragraph [0016] and page 5, paragraph [0020] of the as-filed specification. The MPEP makes clear that "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." MPEP §2163, *citing Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). In the context of the rest of the specification, paragraph [0016] makes clear that the implant body is configured to release the active agent for a time period between 3-6 months, which is why a visit to the eye doctor would only be needed once per 3-6 months.

Accordingly, Applicant respectfully requests that the rejection of claim 22 be withdrawn.

In the Office Action, claim 34 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for insufficient antecedent basis for "implant body" in line 1 of the claim and for "substantially saturated" being a relative term. Although Applicant respectfully traverses this rejection, because the implant body has sufficient antecedent basis and one of ordinary skill in the art understands the metes and bounds of the term "substantially saturated," claim 34 has been canceled, thereby mooting the rejection.

In the Office Action, claims 11, 15, 17, 21, 22, 30, 31, 34, 37, and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by Ness (U.S. Patent No. 3,828,777). Applicant respectfully traverses this rejection.

Claim 11 recites an ocular implant that includes "an implant body extending from a proximal end portion, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion, configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted, the entire implant body comprising a porous or absorbent material; and an active agent disposed entirely throughout the porous or absorbent material so that the entire implant body is saturated with the active agent, the active agent deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system via an exterior surface portion of the implant body." Applicant respectfully submits that Ness does not disclose, teach, or suggest the combination of features recited by claim 11.

Ness discloses an ocular device that includes a body that is "of a shape which is adapted for insertion and retention in the sac of the eye bounded by the surfaces of the bulbar conjunctiva of the sclera of the eyeball and the palpebral conjunctiva of the eye lid." Ness at abstract (emphasis added). Figures 1 and 2 of Ness illustrate the ocular device in the form of an ocular insert 12 in its operative position in the lower sac 11 of the eye. Ness at FIGs. 1 and 2 and col. 3, lines 28-46. Ness does not disclose, teach, or suggest that the ocular device disclosed therein is has an implant body that extends from a proximal end portion, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion, configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted, as recited by claim 11.

Moreover, the body of the ocular insert of Ness is "formed of a drug release rate controlling microporous material that is permeable to the drug by diffusive permeation through a diffusive medium present in the pores of the material." Ness at col. 4, lines 1-5. The diffusive medium, which may be lacrimal or tear fluid, is added to the pores of the microporous material before or at the time the ocular device is inserted in the eye. Ness at col. 7, lines 1-19. Ness does not disclose, teach, or suggest that the entire body of the ocular insert is saturated with an active agent, as recited by claim 11.

In view of the foregoing, Applicant respectfully submits that claim 11 and the claims that depend from claim 11, and include additional advantageous features, are patentable over Ness, and respectfully requests that the rejection of claims 11, 15, 17, 21, 22, and 37 be withdrawn.

Moreover, although claim 22 was rejected as being anticipated by Ness, the Office Action later concedes that "Ness does not explicitly describe a prolonged release time period of active ingredient of 3-6 months," Office Action at page 12, third paragraph, and goes on to assert that it would have been obvious to "prepare an ocular device with a 3-6 month period of drug release." In view of the Office Action's own admission, claim 22 is clearly not anticipated by Ness. Accordingly, the rejection of claim 22 as being anticipated by Ness must be withdrawn for this additional reason.

Claim 30 recites an ocular implant that includes "an implant body sized and shaped for at least partial insertion into a lacrimal canaliculus, the entire implant body comprising a porous or absorbent material; and the porous or absorbent material being saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion

through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent deliverable to tissue at or near one or both of an eye or a nasolacrimal system." Applicant respectfully submits that Ness does not disclose, teach, or suggest all of the features recited by claim 30.

As discussed above, Ness discloses an ocular device for insertion and retention in the sac of the eye bounded by the surfaces of the bulbar conjunctiva of the sclera of the eyeball and the palpebral conjunctiva of the eye lid. The device of Ness does not incorporate a porous or absorbent material that is "saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent deliverable to tissue at or near one or both of an eye or a nasolacrimal system," as recited by claim 30. As such, Ness does not disclose, teach, or suggest an ocular device having the combination of features recited by claim 30.

In view of the foregoing, Applicant respectfully submits that claim 30 and the claims that depend from claim 30, and include additional advantageous features, are patentable over Ness, and respectfully requests that the rejection of claims 30, 31, 34, and 41 be withdrawn.

In the Office Action, claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34, and 37 were rejected under 35 U.S.C. §102(b) as being anticipated by Freeman (U.S. Patent No. 3,949,750). Applicant respectfully traverses this rejection.

Claim 11 is discussed above. Applicant respectfully submits that Freeman does not disclose, teach, or suggest the combination of features recited by claim 11.

Freeman discloses a punctum plug for removably blocking the punctual opening and associated canaliculus for preventing drainage of lacrimal fluid from the eye. Freeman at col. 1, lines 62-65. The punctum plug may serve as a "vehicle for dispensing ophthalmic medication on a sustained release basis by impregnating the plug, or a cellular member attached thereto and resting in the lacrimal lake, with medication which is slowly leached out by the lacrimal fluids." Freeman at col. 2, lines 27-33. Freeman also discloses that "the plugs 20, 20', particularly the head portion 28, 28', may be of medication-impregnable porous material such as HEMA hydrophilic polymer, or may be otherwise adapted as with capillaries or the like, to store and

slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids." Freeman at col. 5, lines 8-14.

Applicant respectfully submits that Freeman does not disclose or teach "an active agent disposed entirely throughout the porous or absorbent material so that the entire implant body is saturated with the active agent, the active agent deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system via an exterior surface portion of the implant body," as recited by claim 11, because contrary to the assertion made in the Office Action at page 8, last paragraph – top of page 9, the active agent of Freeman is not necessarily disposed entirely throughout the porous or absorbent material of the implant body. Moreover, the entire implant body of Freeman is not necessarily saturated with an active agent. Although Freeman discloses that the punctum plug may be used as a vehicle for storing and delivering ophthalmic medication to the eye, Freeman at col. 2, lines 60-65, Freeman specifically teaches that the punctum plug disclosed therein "would prevent drainage and thus systemic absorption of the drug." Freeman at col. 2, lines 33-38 (emphasis added).

In other words, Freeman specifically teaches that the plug is designed to prevent a drug from being delivered to the canaliculus, because if a drug was delivered to the canaliculus, there would be systemic absorption of the drug. Therefore, in view of the overall teachings of Freeman, one of ordinary skill in the art would understand that the entire plug body is not - and should not be - saturated with a drug in order to prevent such systemic absorption. *See* MPEP §2112 ("The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic," citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient,' " quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added)).

In view of the foregoing, Applicant respectfully submits that claim 11 and the claims that depend from claim 11, and include additional advantageous features, are patentable over

Freeman, and respectfully requests that the rejection of claims 11, 14, 15, 17, 21, 22, 29, and 37 be withdrawn.

Claim 30 is discussed above. Applicant respectfully submits that Freeman does not disclose, teach, or suggest the combination of features recited by claim 30.

As discussed above, the entire plug body of Freeman is not necessarily saturated with an active agent, and one of ordinary skill in the art would understand that the entire plug body of Freeman should not be saturated with an active agent. As such, Freeman does not disclose, teach or suggest that the entire implant body comprise a porous or absorbent material, and that the porous or absorbent material be "saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent deliverable to tissue at or near one or both of an eye or a nasolacrimal system," as recited by claim 30.

In view of the foregoing, Applicant respectfully submits that claim 30 and the claims that depend from claim 30, and include additional advantageous features, are patentable over Freeman, and respectfully requests that the rejection of claims 30, 31, 33, and 34 be withdrawn.

In the Office Action, claims 11, 15, 16, 21, 22, 29-31, 33-39, 40-42, and 44 were rejected under 35 U.S.C. §102(b) as being anticipated by Cohan et al. (U.S. Patent No. 6,196,993, hereinafter "Cohan"). Applicant respectfully traverses this rejection.

Claim 11 is discussed above. Applicant respectfully submits that Cohan does not disclose, teach, or suggest the combination of features recited by claim 11.

Cohan discloses an ophthalmic insert 32 that includes a reservoir 34 designed to store and release medication onto the surface of the eye 10. Cohan at col. 4, lines 22-28; FIG. 3. In an embodiment, a wick extension 46 (mislabeled as 40 in FIG. 6) is provided to aid in medication release onto the surface of the eye 10. Cohan at col. 5, lines 21-23; FIG. 6. The wick extension is secured within the reservoir 34 in fluid communication with the medication stored in the reservoir 34 and extends through a pore 42 to rest in the lacrimal lake 12. Cohan at col. 5, lines 24-27; FIGs. 4 and 6.

Applicant traverses the assertion in the Office Action at page 10 that the wick extension of the ophthalmic insert of Cohan has a distal end portion that is configured for insertion through

the lacrimal punctum into a lacrimal canaliculus when implanted. Moreover, Cohan specifically teaches that the wick extension is configured to be inserted through the pore 42 of the insert and secured within the reservoir 34 of the insert. Applicant respectfully submits that the wick extension of the insert of Cohan is not configured to be inserted through the lacrimal punctum into the lacrimal canaliculus, because the wick extension does not have the structure to be inserted through the lacrimal punctum into the lacrimal canaliculus. It is the body potion 36 and enlarged bulb portion 38 of the insert 32 that are configured for insertion through the lacrimal punctum into the lacrimal canaliculus, not the wick extension.

In view of the foregoing, Applicant respectfully submits that claim 11 and the claims that depend from claim 11 are patentable over Cohan, and respectfully requests that the rejection of claims 11, 15, 16, 21, 22, 29, and 37-40 be withdrawn.

Claim 30 is discussed above. Applicant respectfully submits that Cohan does not disclose, teach, or suggest the combination of features recited by claim 30.

As discussed above, Cohan discloses an insert that includes a reservoir in which medication may be stored, and a wick extension that is secured within the reservoir and extends out of a pore so that it may be used to aid in medication release onto the surface of the eye. Cohan does not disclose, teach, or suggest "an implant body sized and shaped for at least partial insertion into a lacrimal canaliculus, the entire implant body comprising a porous or absorbent material; and the porous or absorbent material being saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent deliverable to tissue at or near one or both of an eye or a nasolacrimal system," as recited by claim 30.

In view of the foregoing, Applicant respectfully submits that claim 30 and the claims that depend from claim 30 are patentable over Cohan and respectfully requests that the rejection of claims 30, 31, 33, 34, 41, 42, and 44 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 30, 31, 34, 37, and 41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ness. Applicant respectfully traverses this rejection. As discussed above, claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Ness, because Ness does not disclose, teach, or suggest the combination of

features recited by claims 11 and 30, and also the claims that depend from claims 11 and 30. Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 21, 22, 30, 31, 34, 37, and 41 be withdrawn.

In the Office Action, claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34, 37, 38, 40-42, and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ness in view of Cohan. Applicant respectfully traverses this rejection.

Ness and Cohan are discussed above. Because neither Ness nor Cohan discloses, teaches, or suggests "an implant body extending from a proximal end portion, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion, configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted, the entire implant body comprising a porous or absorbent material; and an active agent disposed entirely throughout the porous or absorbent material so that the entire implant body is saturated with the active agent, the active agent deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system via an exterior surface portion of the implant body," as recited by claim 11, claim 11 and the claims that depend from claim 11 are patentable over Ness in view of Cohan.

Moreover, because neither Ness nor Cohan discloses, teaches, or suggests "an implant body sized and shaped for at least partial insertion into a lacrimal canaliculus, the entire implant body comprising a porous or absorbent material; and the porous or absorbent material being saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent deliverable to tissue at or near one or both of an eye or a nasolacrimal system," as recited by claim 30, claim 30 and the claims that depend from claim 30 are patentable over Ness in view of Cohan.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34, 37, 38, 40-42, and 44 be withdrawn.

In the Office Action, claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34, and 37-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ness in view of Cohan, and further in view

of Robertson (U.S. Patent Application Publication No. 2002/0193441). Applicant respectfully traverses this rejection.

As discussed above, claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Ness in view of Cohan. Applicant respectfully submits that Robertson does not make up for the deficiencies of Ness and Cohan discussed above.

Robertson does not even disclose an ocular implant and is merely used by the Office Action for its teachings of medications for the treatment of glaucoma. *See* Office Action at page 15.

Accordingly, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Ness in view of Cohan and further in view of Robertson, and respectfully requests that the rejection of claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34, and 37-44 be withdrawn.

In the Office Action, claims 11, 15, 16, 21, 22, 29-31, 33, and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Bhushan (U.S. Patent Application Publication No. 2004/0137068). Applicant respectfully traverses this rejection.

As discussed above, claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman. Applicant respectfully submits that Bhushan does not make up for the deficiencies of Freeman.

Bhushan discloses ophthalmic formulations for the prevention and treatment of adverse ocular conditions. Bhushan at abstract. Bhushan discloses that the formulations disclosed therein may be incorporated into an ocular insert for implantation into the conjunctiva, sclera, or pars plan, or into the anterior segment or posterior segment of the eye. Bhushan at [0073]. Bhushan does not disclose, teach, or suggest an ocular implant that includes "an implant body extending from a proximal end portion, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion, configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted, the entire implant body comprising a porous or absorbent material; and an active agent disposed entirely throughout the porous or absorbent material so that the entire implant body is saturated with the active agent, the active agent deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system via an exterior surface portion of the implant body," as recited by claim 11, or an ocular implant that

includes, "an implant body sized and shaped for at least partial insertion into a lacrimal canaliculus, the entire implant body comprising a porous or absorbent material; and the porous or absorbent material being saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent deliverable to tissue at or near one or both of an eye or a nasolacrimal system," as recited by claim 30.

In view of the foregoing, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman in view of Bhushan, and respectfully requests that the rejection of claims 11, 15, 16, 21, 22, 29-31, 33, and 34 be withdrawn.

In the Office Action, claims 11, 15, 17, 22, 29-31, 33, 34, 37, 38, 40-42, and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Cohan. Applicant respectfully traverses this rejection.

Freeman and Cohan are discussed above. Because neither Freeman nor Cohan nor any reasonable combination thereof discloses, teaches, or suggests the combination of features recited by claims 11 and 30, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman in view of Cohan.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 22, 29-31, 33, 34, 37, 38, 40-42, and 44 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 29-31, 33, 34, and 37-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Cohan and further in view of Robertson. Applicant respectfully traverses this rejection.

Freeman, Cohan, and Robertson are discussed above. Because none of Freeman, Cohan, or Robertson, or any reasonable combination of Freeman, Cohan, and Robertson discloses, teaches, or suggests the combination of features recited by claims 11 and 30, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman in view of Cohan and further in view of Robertson.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 21, 22, 29-31, 33, 34, and 37-44 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 29-31, 33, 37, 38, 40-42, and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cohan in view of Bhushan. Applicant respectfully traverses this rejection.

Cohan and Bhushan are discussed above. Because neither Cohan nor Bhushan nor any reasonable combination thereof discloses, teaches, or suggests the combination of features recited by claims 11 and 30, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Cohan in view of Bhushan.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 21, 22, 29-31, 33, 37, 38, 40-42, and 44 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 29-31, 33, and 37-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cohan in view of Robertson. Applicant respectfully traverses this rejection.

Cohan and Robertson are discussed above. Because neither Cohan nor Robertson nor any reasonable combination thereof discloses, teaches, or suggests all of the features of claims 11 and 30, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Cohan in view of Robertson.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 21, 22, 29-31, 33, and 37-44 be withdrawn.

All rejections and objection having been addressed, it is respectfully submitted that the present application is in a condition for allowance and a Notice to that effect is earnestly solicited. If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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